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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,595	10/20/2006	Dominique Petit	BDM-06-1251	8971
35811 7590 06/21/2011 IP GROUP OF DLA PIPER LLP (US) ONE LIBERTY PLACE 1650 MARKET ST, SUITE 4900 PHILADELPHIA, PA 19103			EXAMINER HARVEY, JULIANNA NANCY	
			ART UNIT 3733	PAPER NUMBER
			NOTIFICATION DATE 06/21/2011	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pto.phil@dlapiper.com

Office Action Summary

Application No.

10/590,595

Applicant(s)

PETIT ET AL.

Examiner

JULIANNA N. HARVEY

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20, 22, 23 and 25-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20, 22, 23 and 25-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 37 recites the limitation "a portion of the flexible polymer envelope" in the last two lines. There is insufficient antecedent basis for this limitation in the claim as this claim recites that the envelope is a biocompatible fabric envelope, not a flexible polymer envelope.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20, 22, 23, 25-29, 31-34, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jahng (US 2005/0065516 A1) in view of Baumgartner et al. (EP 0 669 109 A1) and Songer (US 2003/0105459 A1). Regarding **claim 20**, Jahng discloses a connecting element for a spinal fixing system that connects at least two implantable connection assemblies comprising: a cable (32) comprising at least one

elastic strand (para. 0080) at least partly surrounded by and coaxial with a flexible envelope (5; para. 0074) to form a flexible part (8) of the connecting element; and a rigid part (9) having a cavity (see Fig. 7; paras. 0076 and 0078) that at least partly receives the cable such that the cavity receives a portion of the flexible envelope (Figs. 2, 7, and 9). Regarding **claim 22**, Jahng discloses that the cavity is a through cavity or a blind cavity (see Fig. 7; it would be considered a blind cavity). Regarding **claim 23**, Jahng discloses that the cavity is configured to cooperate with the cable (Fig. 7). Regarding **claim 25**, Jahng discloses that the flexible part (8) is fixed to the rigid part (9) by adhesive bonding, crimping, or welding (para. 0076). Regarding **claim 31**, Jahng discloses that the cable (32) comprises strands (para. 0080) and that the strands are made of titanium or stainless steel or titanium-nickel alloy (Fig. 9; para. 0080). Regarding **claim 33**, Jahng discloses that the cable (32) comprises a central strand formed from an alloy of nickel-titanium, titanium, stainless steel or polymer (Fig. 9; para. 0080). Regarding **claim 38**, Jahng discloses a spinal fixing system comprising at least two implantable connection assemblies (2) connected by at least one connecting element according to claim 20 (Fig. 1). Jahng fails to disclose that the flexible envelope is a polymer envelope (**claim 20**), that the cavity has a tapered portion with a widened zone proximal to an end receiving the cable and a narrow zone distal to the end receiving the cable such that the tapered portion receives the portion of the flexible envelope (**claim 20**), that the cable comprises at least one layer of at least six strands distributed around a central strand (**claim 26**), that the cable comprises two layers of strands, the first layer surrounding a central strand and comprising six strands, the

second layer surrounding the first layer and comprising twelve strands (**claim 27**), that the strands constituting the layer or layers comprises strands twisted around the central strand (**claim 28**), that the strands of the layer or layers are formed from a material different from that of a central strand (**claim 29**), that the cable comprises a tubular central strand (**claim 32**), and that the central strand is made from PEEK or polyurethane (**claim 34**). However, Jahng states that the number of strands and the material of the strands can be varied to provide a desired rigidity and flexibility in accordance with a patient's particular needs (para. 0080). Jahng teaches an alternate embodiment wherein the cable (34) is a central strand made from PEEK or polyurethane (para. 0081). Baumgartner et al. teach a connecting element (1, 10) comprising a flexible part (1) comprising a cable (see cross-section 11 for the cable) at least partly surrounded by a polymer envelope (col. 3, line 50 through col. 4, line 9 state that the envelope can be a polymer) (Fig. 6). The cable of Baumgartner et al. comprises two successive layers of strands disposed around a tubular central strand, the first layer of strands surrounding the central strand comprising 6 strands, the second layer of strands surrounding the first layer comprising 12 strands (see cross-section 11) (Fig. 6). The strands constituting the layer or layers comprise strands twisted around the central strand (col. 5, lines 46-58 state that the strands can be braided). Songer teaches an element having a rigid part (28) and a flexible part comprising a flexible cable (22) wherein the rigid part has a cavity (48) having a tapered portion (56) (Fig. 10). The tapered (56) cavity (48) has a widened zone proximal to the end from which the cable (22) extends and a narrowed zone distal to the end from which the cable

extends (Fig. 10). The taper (56) minimizes discrete stress points on the flexible cable (22) (para. 0027). It would have been obvious to one having ordinary skill in the art at the time the invention was for the flexible envelope of Jahng to be a polymer envelope (**claim 20**), as suggested by Baumgartner et al., since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the rigid part of Jahng such that the cavity has a tapered portion with a widened zone proximal to the end from which the cable extends (the end receiving the cable) and a narrowed zone distal to that end (**claim 20**), as suggested by Songer, as such a tapered cavity minimizes discrete stress points on a flexible cable. It would have been obvious to one of ordinary skill in the art at the time the invention was made for the cable to comprise at least one layer of at least six strands distributed around a central strand (**claim 26**), and for the cable to comprise two layers of strands, the first layer surrounding a central strand and comprising six strands, the second layer surrounding the first layer and comprising twelve strands (**claim 27**), as suggested by Baumgartner et al., since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Furthermore, such would be obvious because, as stated by Jahng, the number of strands can be varied to provide a desired rigidity and flexibility in accordance with a patient's particular needs (para. 0080). It would have been obvious to one of ordinary skill in the art at the time the invention was made for the strands

constituting the layer or layers to be twisted around the central strand (**claim 28**), as suggested by Baumgartner et al., as doing so would provide stability and strength to the cable. It would have been obvious to one having ordinary skill in the art at the time the invention was for the strands of the layer or layers to be formed from a material different from that of a central strand (**claim 29**), since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the central strand such that it is tubular (**claim 32**), as suggested by Baumgartner et al., since Applicant has not disclosed that such solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing a central strand for a cable. *In re Dailey and Eilers*, 149 USPQ 47 (1966). It would have been obvious to one having ordinary skill in the art at the time the invention was central strand to be made from PEEK or polyurethane (**claim 34**), since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jahng (US 2005/0065516 A1) in view of Baumgartner et al. (EP 0 669 109 A1) and Songer (US 2003/0105459 A1) as applied to claims 26 and 27 above, and further in view of Mazel (US 5,704,936 A). Jahng, Baumgartner et al., and Songer teach the claimed

invention except that a central strand has a diameter different from that of strands of the layer or layers. Mazel teaches a rod (87) comprising strands (88) wherein a central strand has a diameter different from that of the strands surrounding it (Figs. 27 and 28). It would have been an obvious matter of design choice for a central strand to have a diameter different from that of strands of the layer or layers, as suggested by Mazel, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jahng (US 2005/0065516 A1) in view of Baumgartner et al. (EP 0 669 109 A1) and Songer (US 2003/0105459 A1) as applied to claim 20 above, and further in view of Freudiger (US 2003/0220642 A1). Jahng, Baumgartner et al., and Songer teach the claimed invention except that the envelope is made from polyurethane. Freudiger teaches a flexible rod wherein the rod is made of polyurethane (para. 0013). It would have been obvious to one having ordinary skill in the art at the time the invention was for the envelope to be made from polyurethane, as suggested by Freudiger, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jahng (US 2005/0065516 A1) in view of Baumgartner et al. (EP 0 669 109 A1) and Songer (US 2003/0105459 A1) as applied to claim 20 above, and further in view of Sherman et

al. (US 2005/0085814 A1). Jahng, Baumgartner et al., and Songer teach the claimed invention except that the envelope is made from PEEK. Sherman et al. teach a flexible rod wherein the rod is made of PEEK (para. 0031). It would have been obvious to one having ordinary skill in the art at the time the invention was for the envelope to be made from PEEK, as suggested by Sherman et al., since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jahng (US 2005/0065516 A1) in view of Songer (US 2003/0105459 A1) and Trieu et al. (US 2002/0120270 A1). Jahng discloses a connecting element for a spinal fixing system that connects at least two implantable connection assemblies comprising: a cable (32) comprising at least one elastic strand (para. 0080) at least partly surrounded by and coaxial with a flexible envelope (5; para. 0074) to form a flexible part (8) of the connecting element; and a rigid part (9) having a cavity (see Fig. 7; paras. 0076 and 0078) that at least partly receives the cable such that the cavity receives a portion of the flexible envelope (Figs. 2, 7, and 9). Jahng fails to disclose that the flexible envelope is a biocompatible fabric envelope and that the cavity has a tapered portion that has a widened zone proximal to an end receiving the cable and a narrow zone distal to the end receiving the cable such that the tapered portion receives the portion of the flexible envelope. Songer teaches an element having a rigid part (28) and a flexible part comprising a flexible cable (22) wherein the rigid part has a cavity (48) with a tapered portion (56) (Fig. 10). The tapered (56) cavity (48) has a widened zone proximal to the

end from which the cable (22) extends and a narrowed zone distal to the end from which the cable extends (Fig. 10). The taper (56) minimizes discrete stress points on the flexible cable (22) (para. 0027). Trieu et al. teach a flexible implant wherein the implant is made of a biocompatible fabric (para. 0035). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the rigid part of Jahng such that the cavity is tapered with a widened zone proximal to the end from which the cable extends (the end receiving the cable) and a narrowed zone distal to that end, as suggested by Songer, as such a tapered cavity minimizes discrete stress points on a flexible cable. It would have been obvious to one having ordinary skill in the art at the time the invention was for the envelope of Jahng to be made from a biocompatible fabric, as suggested by Trieu et al., since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

Applicant's arguments filed April 12, 2011 have been fully considered but they are not persuasive. Applicant argues that in combining Songer with Jahng, one skilled in the art would strip a part of the cable of Jahng to allow the cable to flex in the tapered portion of the cavity, and as such, the combination of Jahng, Baumgartner, and Songer would fail to disclose, teach or suggest that the cavity is filled with a part of the flexible polymer envelope (page 6). The examiner respectfully disagrees. First of all, one combining Songer with Jahng would not necessarily strip a part of the Jahng cable. In

fact, it would be much simpler to merely change the size of one of the elements (either the cable or the rigid part) in addition to modifying the cavity to provide the taper in order to allow the cable to flex in the tapered portion of the cavity. Furthermore, Applicant's claims do not recite that the cavity is filled with a part of the flexible polymer envelope. Instead, they merely recite that the tapered portion receives a portion of the envelope, which is satisfied by the combination of Jahng and Songer. If, however, the claims were to recite that the tapered portion of the cavity is filled with a portion of the flexible polymer envelope, Songer would no longer be applicable because Songer requires the cable to flex to minimize stress on the cable.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIANNA N. HARVEY whose telephone number is (571)270-3815. The examiner can normally be reached on Mon. - Fri., 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. N. H./
Examiner, Art Unit 3733
/EDUARDO C. ROBERT/
Supervisory Patent Examiner, Art Unit 3733